

### **DETAILED ACTION**

This office action is a response to Applicant's amendment submitted November 14, 2008, wherein claims 1 and 5 are amended, claim 15 is newly submitted, and claim 3 is cancelled. Claims 1, 2, and 4-15 are pending. Claims 11-14 are withdrawn from consideration as being drawn to a non-elected invention. Claims 1, 2, 4-10, and 15 are examined on the merits herein.

In view of Applicant's amendment submitted November 14, 2008, the rejection of claims 1, 2, 4-8 and 10 under 35 USC 102(b) as being anticipated by Kulbe et al. is withdrawn. As amended, the claims require a degree of crosslinking 30-90%, which is not anticipated by Kulbe et al.

The following new and modified rejections were necessitated by Applicant's amendment submitted November 14, 2008, wherein the limitation "said agent prevents and heals constipation" was added to claim 1, wherein the limitations of claim 3 were incorporated into claim 1, and wherein new claim 15 was added.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4-10, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 4-10, and 15 recite the limitation "said agent prevents and heals constipation." The recitation of "prevents and heals constipation" implies a method step, but claims 1, 2, 4-10, and 15 are written as composition claims. It is unclear whether a composition or a method is being claimed.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4-10, and 15 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kulbe et al. (US 4,689,322, August 25, 1987).

Kulbe et al. teach calcium alginate beads having a diameter of approximately 5 mm. The beads are formed by dropping an aqueous solution of sodium alginate into an aqueous calcium chloride solution [column 14, Example 1]. 50 kg of calcium alginate prepared in this way and 80 kg of water are used to prepare soft gelatin capsules [column 20, lines 5-34].

Kulbe et al. do not teach the degree of crosslinking of calcium alginate hydrogel.

However, considering that the composition of Kulbe et al. is made in substantially the same way as the instantly claimed composition and the claimed degree of crosslinking is quite broad at 30-90%, it is assumed that the composition of Kulbe et al.

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very likely meets the limitations of claim 3. Since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Furthermore, Kulbe et al. teach that the consistency of the gel can be widely varied by variation of the amounts of starting materials [column 5, line 1 - column 6, line 23] and that the gels may be left at a temperature as low as 20°C for as little as 1 hour [column 4, lines 15-21]. These teachings provide guidance for the skilled artisan to optimize Kulbe's conditions.

### ***Response to Arguments***

Applicant argues that Kulbe's product is not made in the same way as the instant invention because Kulbe matures the beads for 12 hours at 4°C. Applicant states that the instant specification teaches that the degree of crosslinking reaches 90% within one hour. The specification also teaches that the degree of crosslinking reaches 30% within 5 minutes and 80% within 30 minutes, which clearly shows that the increase in degree of crosslinking slows dramatically over time. It is unclear whether crosslinking proceeds past 90% within any time frame. Further, because Kulbe's product is matured at low temperature, crosslinking might be expected to proceed more slowly. Thus, Applicant's argument is not persuasive. It is further noted that Kulbe's conditions may be optimized by the skilled artisan, as set forth above.

The following rejection is maintained and modified to include new claim 15:

Claims 1, 2, 4-10, and 15 are rejected under 35 U.S.C. 103(a) as obvious over Aoyagi et al. (US 6,299,867, October 9, 2001, PTO-1449 submitted October 10, 2006).

Aoyagi et al. teach adsorbents formed by coating active carbon with calcium alginate [column 12, Example 7]. The adsorbent is formed by dropping an aqueous solution of sodium alginate and activated carbon into an aqueous solution of calcium chloride to provide gel balls. The active carbon should have a particle diameter in the range of 5  $\mu$ –10 mm [column 4, lines 24-29]. The concentration of aqueous calcium alginate used to form the adsorbent should be in the range of 0.05-5 moles so that the proper amount of cross-linking will be achieved [column 4, line 56 – column 5, line 14]. The adsorbent can be incorporated into foods such as yogurt, jam, jellies, and others in an amount up to 60 wt. % [column 9, line 55 - column 10, line 32].

Aoyagi et al. do not teach the particle size of the adsorbent products and do not teach the degree of crosslinking of sodium alginate used.

Although Aoyagi et al. do not explicitly teach the size of active carbon-containing calcium alginate gel balls obtained in Example 7, it is disclosed that the active carbon, which is coated with calcium alginate, should have a particle diameter in the range of 5  $\mu$ –10 mm. Thus, the products of Aoyagi et al. likely fall within the claimed size range. Furthermore, the skilled artisan could easily arrive at products of the claimed size using the guidance provided regarding particle size of active carbon.

Although Aoyagi et al. do not explicitly teach the degree of crosslinking of calcium alginate, the composition of Aoyagi et al. is made in substantially the same way as the instantly claimed composition. Furthermore, the claimed degree of crosslinking is quite broad at 30-90% and it seems very likely that the calcium alginate of Aoyagi et al. has a degree of crosslinking that falls within this range. Since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

### ***Response to Arguments***

Applicant argues that Aoyagi's example 12 teaches sodium alginate having only 0.3 wt.% of active carbon, which doesn't meet the limitation of claim 9. This argument is not persuasive because Aoyagi teaches that the amount of active carbon can be in the range of 0.02-90 wt.% [column 4, lines 32-39]. Thus, claim 9 is obvious over Aoyagi's teachings.

Applicant argues that the property of preventing and healing constipation is recited in the body of the claim and Aoyagi doesn't teach that property. Applicant's argument is not persuasive because a newly discovered property does not make an old composition patentable. MPEP 2105 states that "the prior art need not disclose a newly discovered property in order for there to be a *prima facie* case of obviousness...if the claimed invention and the structurally similar prior art species share any useful property,

that will generally be sufficient to motivate an artisan of ordinary skill to make the claimed species.”

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on Monday - Friday, 7:00 - 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Shaojia Anna Jiang/  
Supervisory Patent Examiner, Art Unit 1623

/Layla Bland/  
Examiner, Art Unit 1623